



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0885]

Food and Drug Administration Rare Disease Patient Advocacy Day; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting: FDA Rare Disease Patient Advocacy Day. This meeting is intended to enhance the awareness of the rare disease community as to FDA's roles and responsibilities in the development of products (drugs, biological products, and devices) intended for the diagnosis, prevention, and/or treatment of rare diseases or conditions. The goal of this meeting is to engage and educate the rare disease community on the FDA regulatory processes.

This educational meeting will consist of a live and interactive simultaneous Web cast of presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. The interactive meeting will include two general panel discussion sessions, as well as afternoon breakout sessions for more indepth information on the roles of FDA. In addition, onsite attendees will have an opportunity during lunch to engage with FDA and outside experts in a small group setting.

Date and Time: The meeting will be held on March 1, 2012, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. For participants who cannot attend the live meeting, a live interactive Web cast will be made available. Participants may

access this live Web cast by visiting the following site:

<http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/OOPDNewsArchive/ucm277194.htm>.

Contact: Soumya Patel, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm.5279, Silver Spring, MD 20993-0002, 301-796-8660, FAX: 301-847-8621, email: FDAadvocacy@fda.hhs.gov.

Registration: Interested participants may register for this meeting at the following Web site: https://www.team-share.net/FDA_Rare_Disease_Patient_Advocacy_Day_Registration.

If you need sign language interpretation during this meeting, please contact Megan McNamee at mmcnamee@icfi.com by February 15, 2012.

The FDA Rare Disease Patient Advocacy Day is supported by FDA, the National Institutes of Health (NIH), the National Organization for Rare Disorders, and the Genetic Alliance.

FDA encourages all attendees to also plan on attending the NIH Rare Disease Day day-long celebration on February 29, 2011. Please refer to the following Web site for more information regarding the NIH Rare Disease Day event:

<http://rarediseases.info.nih.gov/RareDiseaseDay.aspx>. (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-32436 Filed 12/19/2011 at 8:45 am; Publication Date: 12/20/2011]